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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The primary goal of this research effort is to determine the potential viability of the Lyric device both as a deployable hearing aid for Service Members with existing hearing loss and, in the future, as a possible form factor for a transparent hearing protection device that could protect the hearing of normal-hearing listeners without degrading auditory situational awareness. To this point, significant progress has been made in this evaluation process. The devices have been electroacoustically tested for impulse noise protection, both with C4 and with a blast tube, and they have been found to provide impulse noise protection comparable to commonly-used passive protection earplug devices. Electroacoustic tests in continuous noise, as well as behavioral testing using the Real Ear Attenuation at Threshold method, suggest that continuous noise protection is also comparable to conventional earplug devices. Behavioral testing on listeners with normal hearing suggests that, in the active mode, the devices allow external sounds to pass through at frequencies up to 12 kHz, which provides excellent preservation of situational awareness and localization accuracy comparable to the open ear. An individual who has worn the devices in two combat deployments was identified, and his testimonial appears to provide support for the suitability of the devices for use in military environments. The final component of the study is a field-test for active duty hearing aid users is which is currently in progress at the Walter Reed NMMC.

15. SUBJECT TERMS
Lyric, hearing aid, localization, attenuation

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Introduction: The purpose of the proposed study is to assess the potential military utility of a new hearing aid technology called "extended-wear" that allows a hearing aid to be inserted deeply in the ear canal and left in place continuously for up to 120 days before requiring removal and replacement. We hypothesize that this new extended-wear hearing device can, with little or no modification, be adapted to provide a treatment option for hearing loss that will allow soldiers with mild-to-moderate hearing loss to return to full duty in military environments where standard hearing aid use is not practical. We also hypothesize that, in the longer term, the technologies associated with the extended-wear hearing aid could be adapted to provide long-term hearing protection for listeners with normal hearing with minimal impact on auditory situational awareness and minimal annoyance due to factors related to occlusion, comfort, and device maintenance. We believe that such a system, if it could be achieved, could largely eliminate noise induced hearing loss in battlefield military operations.

Keywords: Hearing aid, situational awareness, Lyric, attenuation, protection, auditory localization, communication, hearing protection, hearing loss, noise exposure, occlusion

Accomplishments:

What were the major goals of the project?

The purpose of this project is to evaluate the potential military utility of the technologies embodied in the revolutionary new "extended-wear" hearing aid. A total of six different types of evaluations will be performed as part of this effort:

1) Evaluate the impact of the devices on sound localization accuracy
2) Evaluate the effect of the devices on occlusion and speech communication in noise
3) Evaluate how well the devices can protect the ear from blast exposure
4) Evaluate how well the devices can protect the ear from noise exposure
5) Evaluate device compatibility with existing military communication systems
6) Evaluate user acceptability of the devices in the hearing-impaired military population

What was accomplished under these goals?

Phase I: Tests of Lyric device on normal hearing participants

Human Research Protocol: An existing protocol used in the routine evaluation of hearing protection devices at the Air Force Research Laboratory (AFRL), Battlespace Acoustics Branch was updated and approved to include the Lyric device. The AFRL protocol was sent to the Human Research Protection Office (HRPO) at the US Army Medical Research & Materiel Command (USAMRMC) and received final approval. Subject recruitment has been initiated. As of June 30, 2017, data collection was completed on ten participants.

Test Plan: A comprehensive test plan is complete for the measurements at AFRL, which will incorporate goals 1-2 and 4-5 above using a normal hearing population; see Table 1 for details. All components of the initial test plan are now complete.

Results: Attenuation is measured for hearing protection devices using the standards developed by the American National Standards Institute (ANSI) published in 2008 and 2012, Methods for Measuring the Real-

Ear Attenuation of Hearing Protectors, and Methods of Estimating Effective A-Weighted Sound Pressure Levels When Hearing Protectors Are Worn, respectively.

The Real-Ear Attenuation at Threshold (REAT) measurement is completed in a sound booth (Figure 1) using Bekesy audiometry. The subject listens to 1/3rd octave-band noise presented from speakers and responds behaviorally by pressing a button when the noise is heard and releasing the button when the noise is not heard. The hearing thresholds, gathered in this manner, for an open ear condition and a closed ear condition (hearing protector) result in the amount of attenuation for a given hearing protection device. Devices are measured with electronics "off" to measure the amount of passive protection (attenuation).

Session:	Measurements
1	Ear exam/cleaning
	Hearing Tests
	REAT training
	Localization training
	VOCRES training
2	Open ear audiometric data
	Open ear REAT thresholds
	Device programming & fitting
	Closed ear REAT thresholds
	Occlusion, aided audiometric data
	Localization/detection
	Communications (listener/talker conditions)
	BREAK
	Closed ear REAT thresholds
	Device removal
	Open ear REAT thresholds
	Questionnaires

Table 1: Test plan overview

Figure 1: Real-Ear-At-Threshold Test Chamber, Air Force Research Laboratory

Ten subjects were tested both in the Real Ear Attenuation at Threshold Method (Figure 3) and by measuring standard audiometric thresholds under a headset while wearing the devices (Figure 4). Both methods show that the extended-wear hearing aid in off-mode provides attenuation comparable to that achieved with a passive earplug.

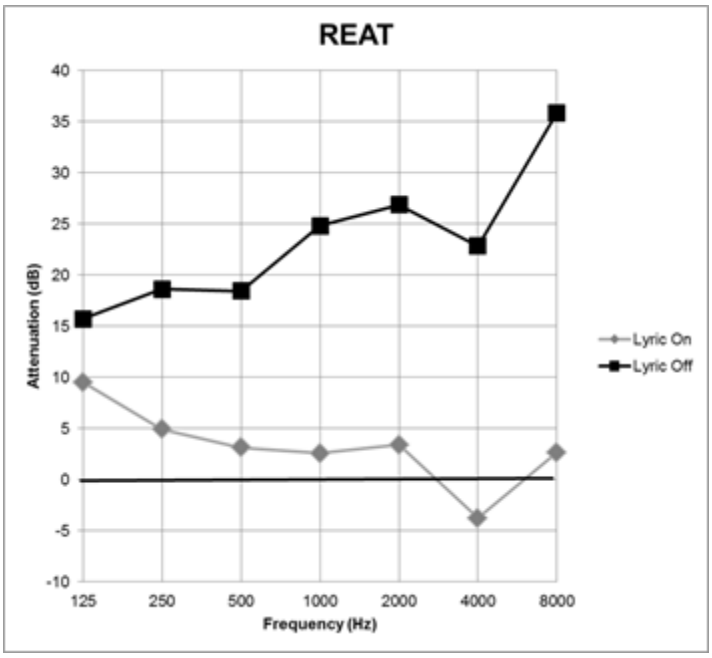


Figure 3: Attenuation of Extended Wear (Lyric) Earplug in Active and Passive Modes, measured using Real Ear Attenuation at Threshold method (in accordance with ANSI S12.6)

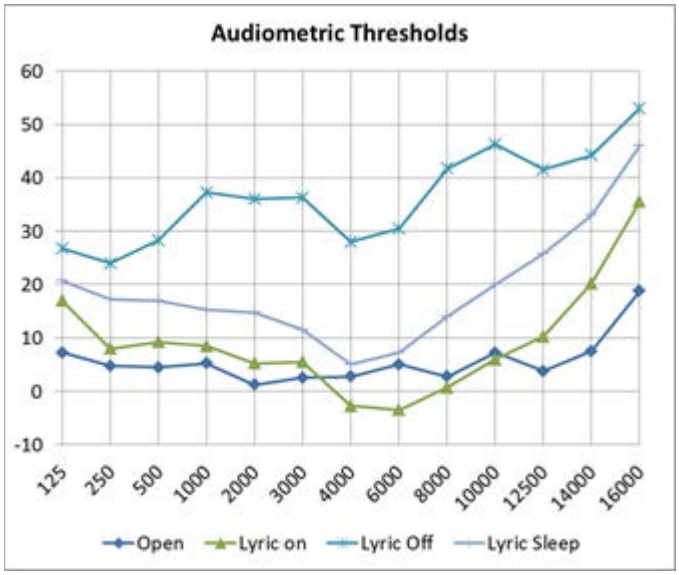


Figure 4: Audiometric thresholds averaged across 10 normal hearing listeners with an open ear and with the Lyric devices inserted in the on, off, and sleep mode.

Localization errors and aurally guided visual search tasks were completed on two subjects in the Spatial Hearing Auditory Research Chamber (SHARC) (Figure 5) at AFRL. The chamber consists of a 32 speaker array in an anechoic chamber. Four light-emitting diodes (LEDs) are located on each speaker. The SHARC is housed within an anechoic chamber. Subjects sit in the center of the array of speakers, and identify the correct speaker either by head pointing or by selecting the speakers by number. Figure 6 shows the mean angular error in the localization measurement for the Lyric device in on, off, and sleep mode, and for three other typical

hearing protection devices. The results clearly show that the Lyric provides superior localization performance in comparison to the other HPD devices. This was especially true for the active TCAP devices.

Figure 5: Spatial Hearing Auditory Research Chamber (SHARC)

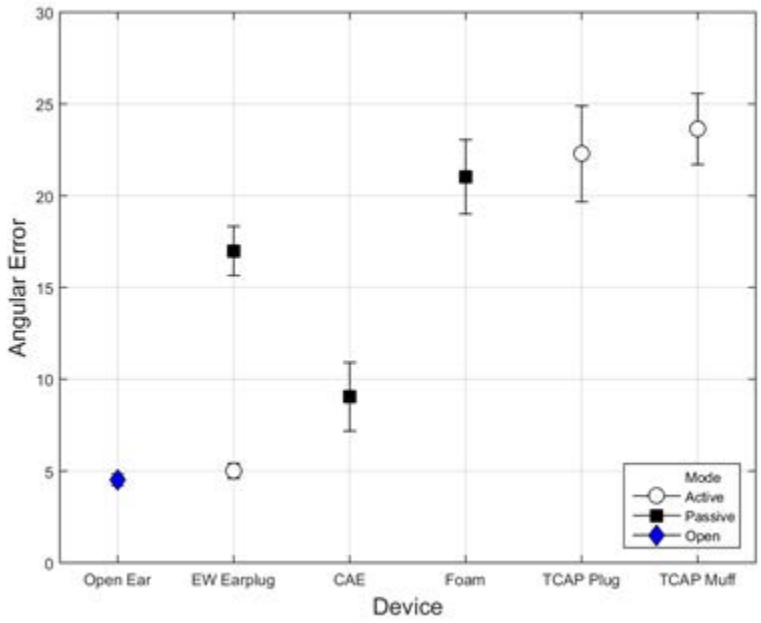


Figure 6: Localization accuracy for identifying the location of a 250ms noise burst in a ring of 32 speakers. The results show that performance in the Lyric (EW Earplug) On condition is slightly worse than open ear, but much better than performance with traditional TCAPs earplug (X50) or TCAP Muff (ComTac III) systems.

For the aurally guided visual search task, response time to aurally locate and visually identify the sound source location was collected for one pilot subject. For this task, the target stimulus was a cluster of LEDs in which either two or four LEDs were illuminated. The distracter stimuli were clusters of LEDs with either one or three illuminated LEDs. In addition, a 250 ms burst of broadband (200 Hz - 16 kHz) pink noise was played from the speaker at the target location at predetermined sound levels of 15, 25 and 40 dB SPL for aided and open ear conditions, and 45 and 65 dB SPL for aided-passive device condition. Results are shown in Figure 10. These results show that the "Lyric On" condition (open circles) was comparable to the open-ear condition at all stimulus levels tested. In comparison, all of the other active protectors tested, including the current US Army TCAPs system (Invisio X50, pink triangles) resulted in a 2-4 substantial increase in visual target acquisition time at 15 dB. At this highest signal level (65 dB), the Lyric in passive (off) mode (blue diamonds) was close to open-ear performance, which was not true for any other protection device. While preliminary, these data suggest that the unique design of the Lyric, which uses an analog amplification circuit that preserves relatively high bandwidth and is inserted deeply in the ear canal where it minimizes the disruption of localization cues, could someday be used to produce a hearing protection system that preserves substantially more situational awareness than any other active or passive hearing protection system currently on the market.

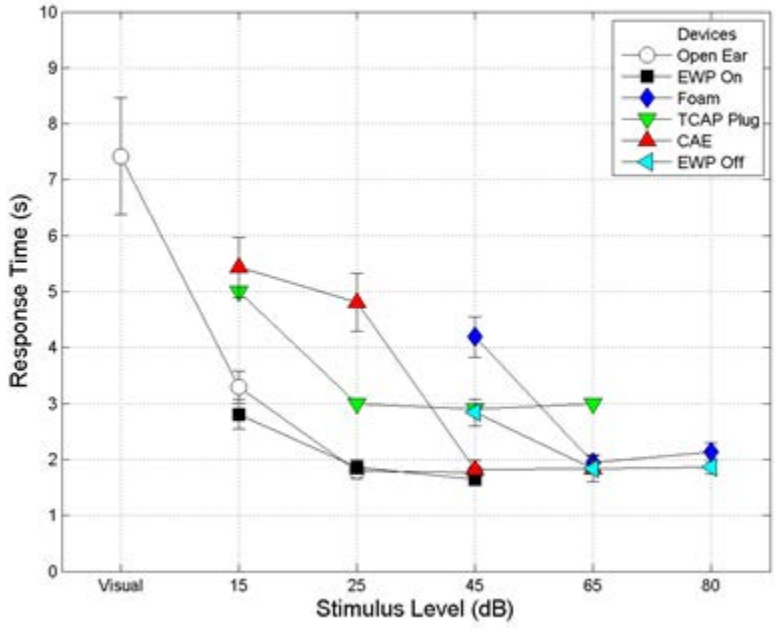


Figure 7: Auditory Localization in an Aurally-Aided Visual Search task as a function of hearing protection devices (as indicated by the legend) and stimulus level (as indicated by the x-axis). The y-axis shows the amount of time it takes for a listener to identify a visual target with 1 or 3 dots at the location of the target sound. The results show that listeners in the EWP (Lyric) conditions (open circles and closed squares) can localize low level auditory targets roughly as quickly and accurately as open-ear targets, and that users of the lyric can localize higher-level targets substantially-faster than other HPDs.

Phase II: Field Test of Lyric device on active duty hearing aid users

Case Study:

A retired service member who used the Lyric hearing aids during two deployments was seen for evaluation at Walter Reed National Military Medical Center in February 2016. The SM had a bilateral sensorineural

hearing loss sloping from moderate to severe degree. A series of measures were made, including functional gain, attenuation provided by the hearing aids when turned off, localization ability, and speech understanding in noise. The results did not indicate that performance with the Lyric was substantially better than performance with a standard hearing aid. Although the SM's hearing loss was outside the range of the target population, his experience indicates that the Lyric could function in deployment.

Full Field Test

Normal Control Group:
To date, seven normal hearing adults have been recruited for testing at Walter Reed National Military Medical Center. Data collection is complete for 5 normal hearing subjects. Testing was conducted for open ear and hearing protection device conditions (TCAP on and TCAP off). The following tests were conducted:

Functional Gain (soundfield): Subjects listened to warbled tones during hearing threshold testing in sound field at 2000, 3000, 4000, 6000, and 8000 Hz in the open ear, TCAP on, and TCAP off conditions. Volume was set to maximum in the TCAP on conditions for all listeners. Subjects were instructed to click the response button when they heard the tones for threshold determination.

Localization: A 27-speaker array arranged at three elevation levels in an arc covering an angle of roughly 270 degrees was used within a sound-attenuating booth for the localization experiment. Subjects were fitted with a head-tracker and given a handheld wand. They were instructed to localize the sound and choose the corresponding speaker within the array by clicking the button the handheld wand. Subjects completed testing in open ear and TCAP full on conditions. The outcome measure was localization accuracy.

Speech in Quiet: NU-6 word lists were presented to subjects in the sound field at a presentation level approximating soft conversational speech (45 dB HL). Subjects completed testing in open ear, TCAP full on volume, and TCAP off conditions. The outcome measure was the proportion of correct words repeated.

Speech in Noise: The standard Quick Speech in Noise (QSIN) was presented to measure speech in noise performance. In this test, masking noise was presented from non-target locations in the array during the presentation of a target sound. Subjects were instructed to repeat the sentences that they heard as accurately as possible. They completed testing in open ear, TCAP full on volume, and TCAP volume off conditions. The outcome measure was the proportion of correct keywords as a function of stimulus and masker configuration.

Acceptable Noise Level: This was tested by presenting diffuse noise from the 27 loudspeakers. Subjects were instructed to increase the volume level to the point where it was "loud but ok". The outcome measure was the sound level selected by the participant in dB SPL.

Experimental Group:
Two participants with hearing loss have been enrolled. The first participant has been using the extended-wear hearing aids for almost 2 months. Subjectively, he likes the hearing aid compared to his standard behind-the-ear hearing aids. The second participant was withdrawn due to an anticipated move out of the country before data collection could be completed.

Participants in the experimental group undergo the test procedures described above, but in addition to open ear and TCAP conditions, they are being tested with the extended-wear hearing aids.

Other Measures, Planned and Completed:
We were able to partner with Rong Gang, who is studying hearing protection in a different MRMC-funded study measuring explosive blast tests involving human cadavers, to examine the impact that a blast of 8.4 dB (189 dB) on a Lyric device inserted in the ear of a human cadaver ear. The results show very little movement of the Lyric device in the human ear canal when exposed to blast (only 0.27 mm), suggesting there is little risk that a Lyric device would be dislodged from the ear canal in a survivable explosive blast. Her data also suggested a total protection from blast of about 16 dB, which was 3 dB higher than for typical passive earplugs.

We hope to be able to conduct some additional follow-on measures at AFRL this year, including localization in elevation and azimuth in the Auditory Localization Facility and REAT testing examining "triple protection" and "double plug" conditions where the Lyric device is combined with other types of hearing protectors.

One desire expressed by our field trial subjects was permission to use the Lyric device in lieu of a hearing protection on firing ranges. All of our data suggests this would be safe, but we are unsure what process would be necessary to advise our subjects try this use case. We are considering an amendment to conduct a walk-up study looking at perceived loudness at systematically decreasing distances of gunshot exposure and retesting hearing after each iteration to insure no TTS is occurring.

What opportunities for training and professional development has the project provided?
The Lyric device is commercially available through Phonak, LLC. Phonak provides regional training for audiologists who fit the Lyric device. Training was provided at AFRL for several audiologists through Phonak's regional consulting audiologist 26-28 May 2015 and again in June 2016.

How were the results disseminated to communities of interest? Our results have been reported at a number of conferences, and we are now preparing manuscripts for the first phase of the study.

Impacts: Nothing to report

Changes/Problems: I think we have made great progress in this study. However, recruiting in our field study has been unacceptably slow, primarily because we selected too low of an age limit for our active duty participants. We have an amendment in place to increase the maximum age to 65, but we are concerned about the timeline of recruiting our cohort of subjects before the end of the study. I fear that we may need to ask for another no-cost extension to complete recruiting in the study.

Products: Nothing to report

Participants & Other Collaborating Organizations:
What individuals have worked on the project?

Name:	Douglas Brungart
Project Role:	Principal Investigator
Nearest person month worked:	1
Contribution to Project:	PI
Funding Support:	Government employee

Name:	Nina Pryor
Project Role:	Associate Investigator
Nearest person month worked:	1

Contribution to Project:	ex-AFRL lead researcher for project
Funding Support:	Funded by award

Name:	Nathan Spencer
Project Role:	Associate Investigator
Nearest person month worked:	1
Contribution to Project:	AFRL lead researcher for project
Funding Support:	Funded by award

Name:	Nandini Iyer
Project Role:	Associate Investigator
Nearest person month worked:	N/A
Contribution to Project:	Consultation support
Funding Support:	Government employee

Name:	LaGuinn Sherlock
Project Role:	Associate Investigator
Nearest person month worked:	N/A
Contribution to Project:	Consultation support
Funding Support:	Government employee

Name:	Ashley Zaleski
Project Role:	Doctoral student
Nearest person month worked:	N/A
Contribution to Project:	Consultation support
Funding Support:	Army Hearing Program

Has there been a change in the active or other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Elizabeth McKenna left the project in March 2016. She was replaced by Nina Pryor, who took another position within AFRL. She was replaced with Nathan Spencer.

What other organizations were involved as partners?

Organization Name:	Integrated Demonstrations and Applications Laboratory, Electromagnetic Interference Research Laboratory, Wright-Patterson Air Force Base, OH
Partner's Contribution:	Facilities and personnel exchanges; completed Electromagnetic Interference laboratory measurements on Lyric device prior to human testing in accordance with MIL-STD 461F.

Organization Name:	Phonak, LLC
Partner's Contribution:	In-kind support; provided on-site training, software and equipment for fitting of Lyric device.

Special Reporting Requirements: N/A

Appendix: Quad Chart

Evaluation of extended-wear hearing aid technology for operational military use

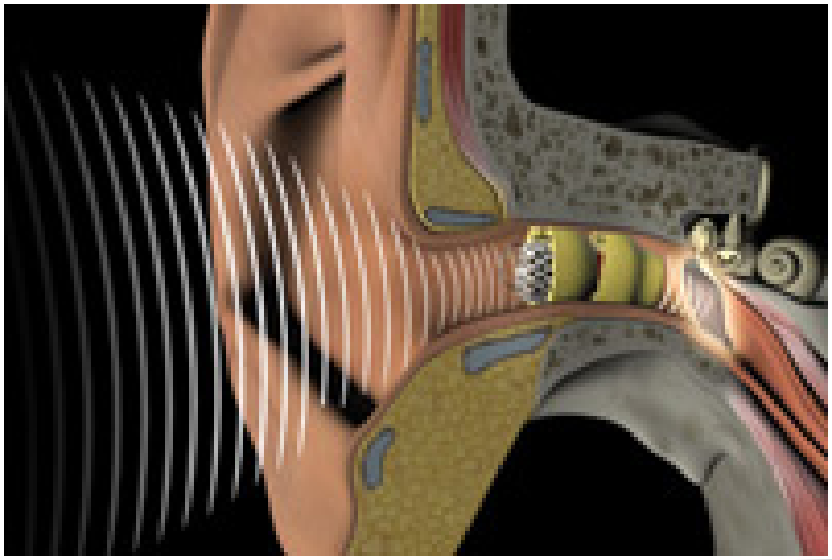
Polytrauma and Blast Injury – Diagnostics, metrics & therapeutics for Hearing Protection

PI: Douglas Brungart **Org:** Henry M. Jackson Foundation

DMRDP

Problem, Hypothesis and Military Relevance

- **Problem**: Hearing loss is the most common injury in the military, in part because current hearing protection systems cannot be worn comfortably for the long periods needed for adequate protection. Also, current hearing aids are incompatible with military operations.
- **Hypothesis**: Extended-wear hearing aid technology may serve as a long-term solution to both of these problems.
- **Military Relevance**: The ability to adequately protect military personnel from noise-induced hearing loss, and to restore functional hearing performance to those who already have hearing loss, is a problem of extreme importance within the US military.



Progress to Date

Data has now been collected on 10 normal hearing subjects at AFRL. The results are promising:

1) Blast and attenuation testing confirms that the device provides passive attenuation comparable to that provided by a standard hearing aid
2) Localization testing indicates that the device produces localization errors comparable to the open ear and *substantially better* than any other active hearing protection device ever tests
3) EFI testing, speech-in-noise testing, and an interview with someone who has used the Lyric in theater appear to confirm feasibility of Lyric for military use and compatibility with other military communication systems and PPE
4) Field testing has received approval is underway

Timeline and Total Cost (direct and indirect)

Activities	FY15	FY16	FY17
Evaluate occlusion, localization, and speech-in-noise perception with device			
Evaluate Noise Protection of Devices by conducting REAT test with devices off			
Evaluate blast protection of devices with deep-in-the-canal test fixture			
Conduct field test of devices in military population			
Estimated Total Budget ($K)	544	419	410